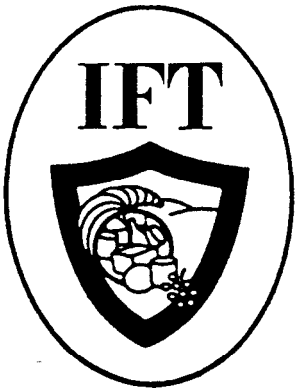

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INSTITUTE OF FOOD TECHNOLOGISTS

Guiding Principles for Optimum Food Safety Oversight and Regulation in the United States

March 1998

Endorsing Scientific Societies (as of 4/3/98)

American Association of Cereal Chemists

American Council on Science and Health

American Dairy Science Association

American Dietetic Association

American Meat Science Association

American Oil Chemists Society

American Society for Clinical Nutrition

American Society of Agronomy

American Society of Animal Science

Crop Science Society of America

Federation of Animal Science Societies

National Association of State Universities and Land-Grant Colleges

Soil Science Society of America

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Guiding Principles for Optimum Food Safety Oversight and Regulation in the United States

Introduction

The Institute of Food Technologists (IFT) applauds the efforts of Congress and the Executive Branch to improve food safety and recognizes the initiatives already taken throughout the food system to reduce the chances of foodbome illness. As the society for food science and technology, IFT represents 28,000 members who work throughout the food system, in industry, academia and government. IFT, which was founded in 1939, brings the scientific perspective to the public discussion of food issues.

IFT believes that the President's artention to food safety, the increased public concern about foodbome illness, and the open acknowledgement among policy-makers of the cumbersome nature of the present food safety system. provide fresh impetus for bold initiatives to improve the oversight of food safety. As an active participant in the food sector, IFT has identified several overarching principles that must form the basis for streamlined and updated oversight of the food system. The principles for appropriate oversight of food safety are that:

- Food safety and public health must be the primary purposes for oversight and regulation of the food system

- Secondary to safety and public health, oversight is appropriate to prevent fraud. promote health, foster global competitiveness of American food and agricultural products, and to ensure harmony among domestic and international food standards

- Oversight for food safety must encompass all components of the food system from production through distribution, imported and domestic foods, science and risk-based regulation for implementing policy, adequate provision for enforcement of regulations, food labeling, intramural research programs, education of regulatory personnel and the public, and communication with the regulated community

- Oversight and regulation must be based foremost on sound science and risk assessment, taking into consideration the costs and benefits of regulations

- Responsibility for oversight to assure food safety must be completely separate from marketing, promotional and industrial policies of all government agencies

- Scientific expertise from academia, industry, professional societies and other state and federal sources must be considered in the development of food policies and regulations

- Oversight policies must be developed in an open and transparent process that considers the views of consumers, producers, processors, retailers and other interested parties in assuring food safety and wholesomeness

- Regulatory agencies must work in cooperation with the regulated food industry to correct for non-compliance with established standards

- Government regulatory agencies must maintain strong and focused intramural research programs while drawing extensively on extramural research from academia, industry and other government/private sources

- Policies and regulations must be crafted with sufficient flexibility to facilitate timely responses to innovations in science and technology

- Oversight policies and regulations must be consistent across any and all agencies responsible for food safety

- Oversight policies and regulations must facilitate and ensure harmony among states and nations

- Safety of foods and ingredients must be based on product characteristics not the process by which the food was grown or produced; establishment of food processing and hygiene controls must be based on objective criteria

Discussion of Principles

- *Food safety andpublic health must be the primary purposes for oversight and regulation of the food system*

The protection of public health is the primary goal of controlling the risks associated with food safety. In setting priorities, assessing other relevant food issues, and developing policy, public health is the first consideration.

- *Secondary to safety and public health, oversight is appropriate to prevent fraud, promote health, foster global competitiveness of American food and agricultural products, and to ensure harmony among domestic and international food standards*

It is recognized that food safety is part of a larger environment of factors that affect public health and the development of food policy. Issues involving food labeling and food

standards illustrate the point. It is appropriate that other closely related factors be considered in the development of food policy in such a way that health and safety are not jeopardized or undermined.

■ *Oversight for food safety must encompass all components of the food system from production through distribution, imported and domestic foods, science and risk-based regulation for implementing policy, adequate provision for enforcement of regulations, food labeling, intramural research programs, education of regulatory personnel and the public, and communication with the regulated community*

Because food safety risks may occur anywhere throughout the food system, oversight must be broad enough to assure that appropriate risk control measures can be implemented where they will be most effective. Oversight must include both domestic and imported foods and ingredients. Regulations governing food safety must be science and risk-based and include adequate provision for enforcement. Food labeling is also within the scope of oversight as it includes factors affecting safety. Intramural research programs are vital to provide the knowledge for science-based decisions, to keep pace with new developments and to determine consumer views. Effective communication of current and new knowledge is critical to ensure that all sectors of the food system have the knowledge necessary to implement food safety practices and that regulators understand how the food system operates. Communication between regulators and the regulated sectors is important to ensure that risk control measures are effective and that enforcement actions are justified. Good communications between regulators and the regulated community can foster cooperation in reducing food safety risks that is ultimately cost effective to all parties. Outreach to the public is important for ensuring that consumers have the knowledge and desire to adopt food safety practices.

■ *Oversight and regulation must be basedforemost on sound science and risk assessment, taking into consideration the costs and benefits of regulations*

Inherent in the concept of food safety are the principles of risk analysis as defined and described in *Issues in Risk Assessment,* National Academy of Sciences (1993). Objective determination of food safety requires assessment of the hazards that may be present in foods and an evaluation of the risk associated with those hazards. Sound scientific data must underlie risk assessments.. Risk analysis should strive to estimate relative rather than absolute risks. Actions should be proportionate to risks and should ensure benefits outweigh risks, thereby providing a return in health and consumer benefits.

■ *Responsibility for oversight to assure food safety must be completely separate from marketing, promotional and industrial policies of all government agencies*

In order to facilitate the development of food policies and regulations that minimize conflicts of interests, food policy shall be established independent of competing govemment programs, private sector interests, or political issues. Consultation with outside groups and the

regulated community during the policy development process will ensure that diverse views will be represented and considered.

- *Scientific expertise from academia, industry, professional societies and other state and federal sources must be considered in the development offoodpolicies and regulations*

Regulatory agencies have unique information requirements. To facilitate science-based decision capabilities, the agency(s) must have adequate resources and in-house scientific espenise. Access to intramural and extramural research is critical to provide the knowledge for science-based decisions. Because the food agency(s) is not necessarily self sufficient, it must be sufficiently funded and structured to draw upon expertise residing in universities, state and other federal agencies, industry, and professional societies. These groups offer a wealth of information, scientific expertise, and practical experience and can provide a perspective that may not exist within the agency(s).

- *Oversight policies must be developed in an open and transparent process that considers the views of consumers, producers, **processors, retailers and other** interested parties in assuring food safety and wholesomeness*

The process for developing policies and regulations must include an opportunity for the public and those affected by the policies and regulations to comment. Provision for input may occur through a system of advisory committees and public hearings on pertinent issues and the solicitation of written comments. The present Food Advisory Cornmirtee of the Food and Drug Administration could serve as an excellent model. The open forums conducted by the U.S. Dept. of Agriculture on Hazard Analysis Critical Control Point (HACCP) and announced to the public via the *Federal Register* also exemplify this kind of activity.

- *Regulatory agencies must work in cooperation with the regulatedfood industry to correct for non-compliance with established standards*

Improvements in the regulated industry's ability to meet performance standards are fostered by cooperative efforts with regulatory agencies. When oversight is established in a constructive atmosphere, both industry and regulatory agency resources are conserved and food safety measures more effectively and quickly achieved. Where there is no immediate public health concern, regulatory personnel should first work with any food company found to be out of compliance with established performance standards to ensure that the company has the knowledge and tools to correct for non-compliance before enforcement procedures are implemented. The regulated industries and the regulatory agencies should be partners in assuring food safety by establishing a cooperative atmosphere.

■ *Government regulatory agencies must maintain strong andfocused intramural research programs while drawing extensively on extramural research from academia. industry and other government/private sources*

Scientific personnel in government regulatory agencies need to build and maintain cutting-edge expertise in scientific issues and need to obtain answers to scientific questions on regulatory issues where knowledge is lacking. Ensuring that regulators are at the forefront of food science will facilitate the timely adoption of new technologies, flexibility in decision-making, and the implementation of research programs to meet critical information needs. Intramural research is essential to address gaps in scientific knowledge related to food safety decision-making, and to facilitate timely decision-making on emerging issues. Intramural research also keeps regulatory personnel in step with developing science. Agencies also need intramural research programs to be able to address issues that would not be attractive research pursuits in the private and education sectors. Agencies should, however, strengthen ties with the extramural research sector and have the flexibility to call on extramural research programs to enhance their intramural research programs.

· Long-term investment in independent scientific research is enhanced by building a strong competitive extramural grant program focused on the research priorities identified by the agency and calling upon independent external experts in the field. The scope of the regulatory agency intramural research program will inevitably be far smaller than that of the extramural information resources. External, scientific advisory panels should guide agencies as research priorities are established.

■ *Policies and regulations must be crafted with sufficient flexibility to facilitate timely responses to innovations in science and technology*

The agency(s) must be capable of assessments that are not only accurate and science-based, but also timely. For example, new methods of pathogen detection and process controls, more precise delineation of pathogenic and non-pathogenic strains of microorganisms and new technologies must be evaluated and regulations updated in a timely manner so as not to impede innovation and freeze safety assessments in obsolete frameworks. In the absence of adequate data for risk and safety assessments, a variety of strategies may be necessary to facilitate timely responses. Timeliness should not come at the expense of scientific assessment and risk analysis but may be facilitated by consultation with extramural expertise. Adequate resources must be available to allow timely yet science and risk-based decisions.

■ *Oversight policies and regulations must be consistent across any and ail agencies responsible for food safety*

Different statutes, divergent interpretations of those statutes and responsibility spread among many agencies contribute to the inconsistency of oversight and regulatory policies governing food safety. Credible scientific data and the principles of risk analysis must be the common base for the oversight of food safety. Regulations that are scientifically indefensible should be revised to be consistent with current science and risk analysis or abolished. The

recently adopted Hazard Analysis Critical Control Points (HACCP) approach for the safety of meat, poultry and seafood is an example of science and risk-based regulation supported by virtually all scientific bodies and the regulated sector and promulgated by both USDA and FDA. Consistency in oversight and regulation would be enhanced if responsibility for food oversight were focused in a single policy/regulatory unit that tightly adhered to objective criteria and risk analysis.

■ *Oversight policies and regulations must facilitate and ensure harmony among states and nations*

Sound, science-based food safety principles should transcend state, national and international boundaries. Indeed, with the explosive expansion of trade. it is imperative that food safety regulations be harmonized internationally to protect consumers in impcning countries and to facilitate free trade. Risk analysis is the fundamental methodology supporting the food safety standards being developed for international trade by the Codex Alimentarius Commission of which the United States is a member. The United States should provide strong leadership in harmonizing food regulations internationally and in asserting the primacy of science-based policy through the example of its own policies and in the Codex forum. A prerequisite for the United States to provide leadership internationally, however, is to establish a sound science-based food safety system at the federal level and to ensure that an effective partnership is in place with state agencies. Such a system provides a model for others to emulate and improve.

The United S fates actively participates in the deliberations of the Codes Alimentarius Commission. Codes is an open forum where governments and non-government observer organizations reach consensus on food standards, codes of practice, and other guidelines that affect trade and public health within and between nations.

■ *Safety assessment of foods and ingredients must be based on product characteristics not the process by which the food was grown or produced; establishment offoodprocessing and hygiene controls must be based on objective criteria*

Applying accepted principles of toxicology, the safety of a food or ingredient is determined according to its chemical, toxicological and microbiological characteristics, not the methods by which the food was produced. Adhering to the principle of "product not process" assures that safety is determined according to science and risk assessment, not factors that may be unrelated to safety. This principle is especially germane to the applications of agricultural biotechnology. It is recognized that many food manufacturing processes may themselves be regulated to ensure safe food products, e.g., time and temperature controls. Criteria for oversight of such processes must be grounded in science.